



PATENT
Docket No. C 2290 COGG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Mehdi Bonakdar, et al.

Serial No. 09/923,626

Examiner: Sabiha N. Qazi

Filed: 08/07/01

Art Unit: 1616

TITLE: PROCESS FOR THE PRODUCTION OF STEROLS

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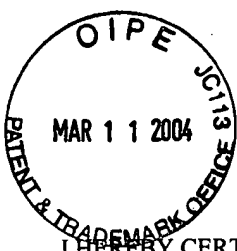
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BY: Rose A. Stowe DATE: March 9, 2004
Rose A. Stowe

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Patent Application of	: Group Art Unit: 1616
	Mehdi Bonakdar, <i>et al.</i>	:
		:
Appln. No.:	09/923,626	: Examiner: Sabiha N. Qazi
		:
Filed:	August 7, 2001	: Confirmation No.: 2081
		:
For:	PROCESS FOR THE PRODUCTION OF	: Attorney Docket
	STEROLS	: No.: C 2290 COGG

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Pursuant to the Notice of Appeal filed on October 9, 2003, via facsimile, and received by the U.S. Patent & Trademark Office on the same date, Appellants submit herewith a Brief On Appeal under 37 C.F.R. §1.192, appealing the Examiner's final rejection of pending claims 1-19 as set forth in the final Office Action dated April 9, 2003 (Paper No. 10), as maintained in the Advisory Action dated September 29, 2003 (Paper No. 13). This Brief On Appeal is being timely filed as a Petition for a three-month extension of time, up to and including March 9, 2004, including an authorization to charge fees, is being submitted herewith.

Appellants respectfully request consideration by the honorable Board of Patent Appeals and Interferences and reversal of the Examiner's rejection of all pending claims based on the arguments set forth in the attached brief.

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REAL PARTY IN INTEREST

The real party in interest in the instant appeal is Cognis Deutschland GmbH & Co. KG, a German company having a place of business at Henkelstraße 67, 40589 Düsseldorf, Germany.

RELATED APPEALS AND INTERFERENCES

Appellants are aware of the appeal in co-pending U.S. patent application serial number 09/923,629, pending before Examiner Badio in Group Art Unit 1616, which may directly affect or may be directly affected by or may have a bearing on the Board's decision in the instant appeal. Appellants are not aware of any other related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

STATUS OF THE CLAIMS

Claims 1-19 are pending in the instant application on appeal. All of the pending claims are the subject of the instant appeal. Claims 1-19 stand finally rejected under 35 U.S.C. §103(a), as being unpatentable over "Fizet (abstract of EP 610742, U.S. Patent 5,487,817)", for the reasons of record set forth in Paper No. 10 and Paper No. 13. All references to "Fizet" made herein are directed to the column and line numbers of the U.S. Patent.

STATUS OF AMENDMENTS

No amendments have been filed in the instant application on appeal subsequent to the Examiner's final rejection of claims 1-19. Appellants' Request for Reconsideration After Final, filed on August 8, 2003 ("the Request for Reconsideration After Final"), has been considered but was not deemed to place the instant application in a condition for allowance, as indicated in Paper No. 13. An appendix containing a copy of the claims involved in the appeal, in accordance with 37 C.F.R. §1.192(c)(9), is attached as Appendix A.

SUMMARY OF THE INVENTION

Appellants' invention is directed to sterol production and more particularly to a process for the production of sterols from residues of the distillation of transesterified oils. (*See*, Appellants' Specification, p. 1, lines 23-25). Appellants' claimed invention is an economic and ecological improvement over the prior art processes in that harsh solvents are avoided and higher purity is more easily attained. (*See, id.* at p. 1, lines 4-21).

Appellants have discovered that a process for the production of sterols can be made more economical and friendlier to the environment by combining two separate transesterification steps. (*See, id.* at p. 2, lines 27-29). In the first transesterification step, the mono-, di- and triglycerides present in the oil distillation residue are reacted with a lower alcohol in the presence of a basic catalyst. Under the mild conditions, the sterol esters remain predominantly bound and only a small amount of free sterols is formed (< 1% by weight). (*See, id.* at p. 2, line 29, through p. 3, line 1). Following the first transesterification, and after removal of the excess alcohol, transesterification catalyst and glycerol, the fatty acid esters are distilled, resulting in concentration of the sterol esters at the bottom of the column. In a second transesterification step carried out under more extreme conditions, the sterol esters are then split into the free sterols. (*See, id.* at p. 3, lines 1-5). Because the impurities have been removed from this second transesterification step and the sterol esters are present in concentrated form, the free sterols can be obtained under far more economic conditions. (*See, id.* at p. 3, lines 5-8).

More specifically, one embodiment of Appellants' claimed invention is directed to processes for producing sterols, the processes comprising:

- (a) providing an oil distillation residue, said residue comprising sterol esters and partial glycerides;
- (b) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst under mild transesterification conditions to form fatty acid alkyl esters and glycerol;
- (c) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol

esters; and

- (d) transesterifying the sterol esters at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar for a period of from 4 to 10 hours to form free sterols.

(See, Appendix A of this Brief on Appeal, claim 1).

As explained above and in Appellants' Specification, Appellants' claimed invention provides an economical and ecologically improved process which begins with an oil distillation residue containing sterol esters and partial glycerides. The oil distillation residue is then subjected to a *first* mild transesterification to split the glycerides into fatty acids and glycerol. These components can then be removed, for example, via distillation. The remaining sterol esters can then be subjected to a *second* transesterification apart from the original complex mixture of glycerides, waxes and other components present in the oil distillation residue.

Appellants' invention is a significant improvement over the prior art processes wherein complex mixtures of sterol esters, glycerides, other waxes and numerous other high-molecular weight substances are all simultaneously subjected to a single harsh transesterification.

ISSUE

- (1) Is the disclosure of the Fizet reference insufficient to establish a *prima facie* case of obviousness with respect to the claimed invention?

GROUPING OF THE CLAIMS

All of the pending claims stand or fall together for the purposes of the instant appeal.

ARGUMENT

I. The Examiner's Rejection Under 35 U.S.C. §103(a) is Improper

A. The Rejection of Claims 1-19 Over Fizet:

In Paper No. 13, the Examiner maintains the rejection of claims 1-19 under 35 U.S.C. §103(a), as being unpatentable over Fizet for the reasons of record set forth in Paper No. 10 and the Office Action mailed September 10, 2002 (Paper No. 8).

In Paper No. 10, the Examiner contends that Fizet discloses a process for recovering tocopherols and sterols from natural sources, and she argues that this disclosure somehow “embraces Applicant’s [sic] claimed invention.” (See, Paper No. 10, p. 3). The Examiner further contends that Fizet discloses a process “for isolation of sterols” which includes (a) esterifying sterols with fatty acids, (b) distilling the resulting mixture to produce a residue of sterol esters, (c) cleaving the sterol esters to form free sterols and (d) isolating the sterols from the residue.

The Examiner then contends that the instant claims differ from the prior art only in that they cite conditions for the reactions and classify the cleavage of the ester as transesterification. The Examiner then summarily argues that “[i]t would have been obvious to one skilled in the art at the time of invention to isolate sterols from the mixture by first transesterif[ying] the mixture to get the sterols esters and then separating other products by distillation or any other means and then cleaving the sterol to break the ester bond with sterol to get free sterol.” (See, *id.* at p.3).

On this basis, the Examiner concludes that the subject matter of the instant claims would have been obvious within the meaning of 35 U.S.C. §103(a).

B. Appellants' Traversal:

Appellants respectfully traversed the Examiner's rejection in the Amendment After Final, and initially in Appellants' Request for Reconsideration, filed on January 10, 2003, in response to Paper No. 8.

Appellants again strenuously, but respectfully, traverse the Examiner's rejection and the contentions and arguments in support thereof, for the reasons set forth below.

C. Law Regarding Prima Facie Obviousness:

In order for an Examiner to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

D. Lack of Prima Facie Obviousness:

Appellants respectfully submit that none of the three requirements for establishing a *prima facie* case of obviousness has been satisfied based upon the cited reference. Fizet fails to teach or suggest each and every element of Appellants' claimed invention. Fizet does not contain any teaching or suggestion which would motivate one of ordinary skill in the art to modify its teachings as needed to arrive at the claimed invention. Finally, Fizet does not contain any teaching or suggestion which would provide one of ordinary skill in the art with a reasonable expectation of successfully preparing sterols by deviating from the express teachings thereof.

Fizet fails to disclose a process for isolating sterols from an oil distillation residue containing sterol esters and partial glycerides, wherein two separate transesterifications, under different conditions are carried out, as claimed.

In contrast, what Fizet discloses is a process for recovering tocopherols and, optionally, sterols *from deodorizer sludges*. Fizet discloses the removal of tocopherols from deodorizer sludges via the direct esterification of sterol with fatty acids present in the sludge. The residue left after the distillation of the tocopherols (*i.e.*, the oil distillation residue) is subjected to a **single**, harsh transesterification.

Ultimately, the oil distillation residue produced via the process disclosed in Fizet, and which contains "the majority of sterol esters which are formed in the [initial direct]

esterification” is subjected to a single transesterification, whereby the yield of sterols is optimized via catalysts, solvents and harsh reaction conditions. (*See*, Fizet, col. 5, lines 46-67). Appellants’ claimed invention is an economic and ecological improvement over such prior art processes in that such solvents are avoided and higher purity is more easily attained. (*See*, Appellants’ Spec., p. 1, lines 4-21).

Fizet discloses a process which begins with a deodorizer sludge containing tocopherols, sterols, fatty acids and other components. The sterols present in the sludge are first esterified with fatty acids present in the sludge, *i.e.*, a direct esterification. This esterified sludge containing sterol fatty acid esters, fatty acids, tocopherols and various other components is then distilled twice to remove a first fraction containing fatty acids, and a second fraction containing tocopherols. (*See, e.g.*, Fizet, claim 1, subsection (b)). The eventual residue obtained after the distillations and other processes designed to remove the tocopherols, (*i.e.*, the oil distillation residue), contains sterol fatty acid esters along with triglycerides, other waxes, and numerous other high-molecular weight substances. (*See*, Fizet, col. 5, lines 46-53). Fizet discloses that sterols may be obtained from the residue via acid-catalyzed transesterification carried out in a steel autoclave over a period of from 1 to 5 hours. (*See, id.* at lines 53-64). This harsh, single transesterification step wherein glycerides, tocopherol esters, sterol esters and numerous other substances are all simultaneously transesterified is avoided by Appellants’ claimed invention.

Appellants’ claimed invention provides a process which begins with an oil distillation residue containing sterol esters and partial glycerides. The oil distillation residue is then subjected to a first mild transesterification to split the glycerides into fatty acids and glycerol. These components can then be removed, for example, via distillation. The remaining sterol esters can then be transesterified apart from the original complex mixture of glycerides, waxes and other components present in the oil distillation residue. More specifically, Appellants’ claimed invention is a surprisingly economical and environmentally friendly process for producing sterols comprising two separate transesterification steps. (*See*, Appellants’ Specification, page 2, lines 25-27).

Fizet clearly fails to teach or suggest each and every element of Appellants’ claimed invention. First, Fizet does not teach or suggest the transesterification of an oil

distillation residue containing sterol esters and partial glycerides under mild conditions whereby the sterol esters remain substantially bound as esters. Such a transesterification is not even suggested. Fizet clearly teaches the treatment of the sterol ester-containing residue via a single transesterification to obtain free sterols. Furthermore, the reference fails to suggest a two-step transesterification with an intervening separation of glycerol and other unwanted compounds from the sterol esters. Fizet specifically provides for sterol yield optimization through the solvent/catalyst/reaction condition options which are avoided by Appellants' claimed process. (See, Fizet, col. 5, lines 64-67).

Moreover, Fizet contains no teaching or suggestion which would motivate one of ordinary skill in the art to modify Fizet as suggested by the Examiner in order to arrive at Appellants' claimed invention. Fizet does not teach or suggest subsequent treatment of the sterol ester-containing residue other than the single harsh transesterification. The residue is simply transesterified under normally harsh conditions *whereby all substances are simultaneously transesterified*, and subsequent purification, *e.g.*, via crystallization, is performed. Nothing in Fizet suggests the claimed two-step transesterification. Nor is there any suggestion that the sterol esters should be concentrated prior to final transesterification via Appellants' claimed mild transesterification and separation of glycerol, etc. Fizet clearly recognizes the presence of many other compounds in the sterol ester-containing residue.

Given the lack of any teaching or suggestion to modify the reference as suggested by the Examiner, and that fact that the reference otherwise fails to teach or suggest each and every element of the claimed invention, one of ordinary skill in the art would find no reasonable expectation of successfully achieving the claimed invention in the teachings of Fizet.

Accordingly, Appellants submit that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied.

CONCLUSION

In view of the arguments set forth above, Appellants submit that the Examiner's rejection under 35 U.S.C. §103(a) is improper in that the Examiner has failed to establish a *prima facie* case of obviousness, and that all claims on appeal patentably distinguish over the prior art of record and known to Appellants, either alone or in combination. Accordingly, Appellants respectfully request that the Board find for Appellants and reverse the Examiner's final rejection.

Respectfully submitted,

MEHDI BONAKDAR, et al.

March 9 2004
(Date)

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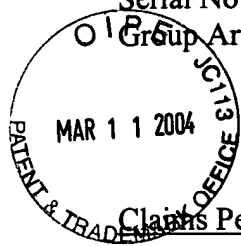
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APPENDIX A

Claims Pending in the Instant Application On Appeal:

1. A process for producing sterols, said process comprising:
 - (a) providing an oil distillation residue, said residue comprising sterol esters and partial glycerides;
 - (b) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst under mild transesterification conditions to form fatty acid alkyl esters and glycerol;
 - (c) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters; and
 - (d) transesterifying the sterol esters at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar for a period of from 4 to 10 hours to form free sterols.
2. The process according to claim 1, wherein the oil distillation residue is vegetable oil-derived.
3. The process according to claim 1, wherein the oil distillation residue comprises a residue derived from an oil selected from the group consisting of soybean oil, sunflower oil, rapeseed oil, coconut oil, palm oil, palm kernel oil, and mixtures thereof.
4. The process according to claim 1, wherein the transesterification of the partial glycerides under mild conditions is carried out at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar, for a period of from 5 to 20 minutes.

5. The process according to claim 1, wherein the transesterification of the partial glycerides under mild conditions is carried out at a temperature of from 120°C to 130°C and a pressure of from 2 to 10 bar, for a period of from 8 to 15 minutes.

6. The process according to claim 1, wherein the lower alcohol comprises methanol.

7. The process according to claim 1, wherein removing excess lower alcohol comprises allowing expansion until the reaction temperature has cooled to a temperature of from 65°C to 85°C.

8. The process according to claim 4, wherein the lower alcohol comprises methanol.

9. The process according to claim 4, wherein removing excess lower alcohol comprises allowing expansion until the reaction temperature has cooled to a temperature of from 65°C to 85°C.

10. The process according to claim 1, wherein the removal of the basic catalyst comprises the addition of an aqueous solution of an acid, precipitation of the catalyst and separation of the precipitate.

11. The process according to claim 1, wherein the fatty acid alkyl esters are removed by distillation.

12. The process according to claim 11, wherein the distillation is carried out at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar.

13. The process according to claim 4, wherein the fatty acid alkyl esters are removed by distillation.

14. The process according to claim 13, wherein the distillation is carried out at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar.

15. The process according to claim 8, wherein the fatty acid alkyl esters are removed by distillation.

16. The process according to claim 15, wherein the distillation is carried out at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar.

17. The process according to claim 1, wherein the transesterification of the sterol esters is carried out at a temperature of from 120°C to 130°C and at a pressure of from 2 to 10 bar, for a period of from 5 to 8 hours.

18. The process according to claim 1, further comprising purification of the free sterols via crystallization and washing.

19. A process for producing sterols, said process comprising:
(a) providing an oil distillation residue derived from an oil selected from the group consisting of soybean oil, sunflower oil, rapeseed oil, coconut oil, palm oil, palm kernel oil, and mixtures thereof, said residue comprising sterol esters and partial glycerides;

(b) transesterifying the partial glycerides and the free fatty acid-based partial glycerides with methanol in the presence of a basic catalyst at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar, for a period of from 5 to 20 minutes, to form fatty acid methyl esters and glycerol;

(c) removing excess methanol, the basic catalyst, and the glycerol, and distilling off the fatty acid methyl esters at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar, to form a bottom product comprising the sterol esters; and

(e) transesterifying the sterol esters at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar for a period of from 4 to 10 hours to form free sterols.